

REMARKS

This is in response to the Office Action dated November 13, 2009. Claim 14 has been cancelled without prejudice or disclaimer. Claims 1, 22, 45, and 47 have been amended herein. Claims 22-45 and 47-55 are withdrawn. Support for the amendments to claims 1 and 22 can be found in at least originally filed claim 14. Claim 45 has been amended to remove a comma. Claim 47 has been amended to now depend from claim 45. No new matter has been added by this amendment. Reconsideration of the present application is respectfully requested in view of the above amendments and the following remarks.

RESPONSE TO OFFICE ACTION'S ARGUMENTS

On pages 7, fifth paragraph to page 9, second paragraph, the Office Action generally states that U.S. Patent No. 6,027,946; U.S. Patent No. 6,548,264; and U.S. Patent No. 5,445,970 disclose the use of ferromagnetic, ferromagnetic material, magnetite and appears to conclude that these materials are remanent. A Declaration under 37 C.F.R. § 1.132 ("Declaration") filed herewith in section 3 provides an explanation of differences between superparamagnetic and remanent material. The Declaration further explains that ferromagnetic and ferrimagnetic materials are capable of exhibiting superparamagnetic or remanent behavior. Accordingly, as discussed in section 3.5 of the Declaration, a simple disclosure of a ferromagnetic or ferrimagnetic material or magnetite is not necessarily disclosure of a remanent material or a material capable of exhibiting remanence, as discussed in detail below.

REJECTIONS UNDER 35 U.S.C. § 102

A. Claims 1-9, 11, and 13-19 stand rejected under 35 U.S.C. § 102(b) for alleged anticipation by Weitschies *et al.* (U.S. Patent No. 6,027,946). Applicants traverse this rejection and submit that the instant claims are novel over Weitschies *et al.*

Weitschies *et al.* fail to disclose the limitations of claim 1. Claim 1 recites, among other things, a magnetic particle comprising a magnetic material ***which is remanent upon exposure to a magnetic field***, such that the particles form aggregates when suspended in the liquid phase in the absence of a magnetic field but are dispersible upon application of a force to

disrupt the aggregates, and a matrix material which has a surface comprising functional groups which promote disaggregation of the particles in the presence of a liquid phase.

In contrast, Weitschies *et al.* teach the use of *superparamagnetic* material, *i.e.*, material that is **not remanent** upon exposure to a magnetic field. Declaration in Section 4 explains that in order for the method of Weitschies to work, the materials used need to be superparamagnetic. In particular, as set forth in section 4.2 of the Declaration, Weitschies *et al.* require the use of magnetic material which exhibits relaxation of magnetisation over the period the method is performed. The method thus needs to be performed with superparamagnetic materials, which are capable of such relaxation. This understanding is supported by the examples of Weitschies which, as discussed in section 4.3 of the Declaration, are performed with dextrancoated magnetic material which is superparamagnetic. Further, as discussed in section 4.4 of the Declaration, the disclosure in Weitschies *et al.* is directed to the need for the colloidal suspensions of the particles to be "freely moveable" (see, *e.g.*, column 6, lines 13 to 15). Remanent particles that cause aggregation in the liquid phase are not "freely moveable". Accordingly, Weitschies *et al.* fail to disclose particles that comprise magnetic material which is remanent.

As discussed in column 3, lines 20 to 41 of Weitschies *et al.*, an important principle of the detection methods is that after the external magnetic field is turned off, the magnetization of the particles relaxes *within the measuring time* by (i) Brownian relaxation or extrinsic superparamagnetism, and (ii) Neelian relaxation or intrinsic superparamagnetism. To obtain useful measurements, this method requires the magnetic particles to have a measurable Neelian relaxation over a relatively short time after the magnetic field is switched off. Hence, by requiring short Neelian relaxation times, the magnetic particles of Weitschies *et al.* do not have significant remanence because from a practical perspective, remanence would interfere with the measurements described therein.

Applicants submit that the claimed magnetic particles comprising a magnetic material that is remanent upon exposure to a magnetic field such that the particles form aggregates when suspended in a liquid phase in the absence of a magnetic field, would necessarily have Neelian relaxation times on the order of several months, even several years,

making them different than the preferred particles of Weitschies *et al.* Given this inherent difference, which would render the instant magnetic particles unsuitable for the methods of Weitschies *et al.*, Applicants submit that the particles of Weitschies *et al.* do not anticipate the subject matter of claim 1.

Applicants, therefore, submit that the instant claims satisfy the requirements of novelty over Weitschies *et al.*, and respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

B. Claims 1-5, 7-18, and 21 stand rejected under 35 U.S.C. § 102(e) for alleged anticipation by Tan *et al.* (U.S. Patent No. 6,548,264). Applicants respectfully traverse this rejection and submit that the claims 1-5, 7-18, and 21 are novelty over Tan *et al.*

Tan *et al.* fails to disclose particles having both the claimed magnetic material and the claimed matrix material. The disclosure of Tan *et al.* relates generally to the field of nanoparticles and methods of making nanoparticles, and discloses nanoparticles for use in a large variety of different fields, including semiconductor particles, dye-doped particles, pigment particles, *etc.*, as well as magnetic particles. It is only in a few variations that Tan *et al.* disclose particles with cores that can be magnetic. (see, *e.g.*, column 2, lines 27 to 29) As explained in section 5.2 of the Declaration, the example magnetic nanoparticles of Tan *et al.* are produced by a method which generates superparamagnetic materials (ferrofluids). Indeed, the particles having remanent magnetisation are only mentioned in the context of particles which are useful in binary magnetic recording applications. (see, *e.g.*, Tan *et al.*, column 12, third paragraph, Declaration, section 5.1) Binary data storage is clearly different from the use of magnetic particles for use in a liquid phase in a binding of a nucleic acid to allow the nucleic acid to be separated from the sample as set forth in claim 1. Indeed, magnetic particles for a binary magnetic recording application, such as those disclosed in Tan *et al.*, may not be capable of binding to a nucleic acid. (see Declaration, section 5.1) Furthermore, there is no indication that the remanent particles of Tan *et al.* would have functional groups necessary to promote disaggregation in a liquid phase. (see Declaration, section 5.1) A person of skill in the art would understand that the functional groups of Tan *et al.* are to be used in binding a secondary ligand.

Accordingly, Applicants submit that the instant claims satisfy the requirements of novelty over Tan *et al.*, and respectfully request withdrawal of this rejection under 35 U.S.C. § 102(e).

C. Claims 1-19 and 21 stand rejected under 35 U.S.C. § 102(b) for alleged anticipation by Rohr (U.S. Patent No. 5,445,970). Applicants traverse this rejection and submit that claims 1-19 and 21 are novel over Rohr.

Rohr fails to disclose a magnetic particle comprising a magnetic material *which is remanent upon exposure to a magnetic field*, such that the particles form aggregates when suspended in the liquid phase in the absence of a magnetic field but are dispersible upon application of a force to disrupt the aggregates, and a matrix material which has a surface comprising functional groups which promote disaggregation of the particles in the presence of a liquid phase.

It is respectfully pointed out that disclosure of a ferromagnetic/ferrimagnetic material, or magnetite, does not directly and unambiguously disclose a magnetic material which exhibits remanence. As discussed in section 6.1 of the Declaration, the purpose of using magnetically attractable material in the Rohr method is to provide a detectable label in binding assays, and the effect of the magnetic field on the magnetically-attractable label is used as a measure of the presence or amount of an analyte in a test sample. One of ordinary skill in the art would understand that the Rohr method has no need for the particles to exhibit remanence, and would further consider remanence to be disadvantageous due to aggregation of particles. Additionally, one of ordinary skill in the art would be deterred from using magnetic materials because the examples of Rohr disclose using superparamagnetic particles, especially when considering the general view in the state of the art as discussed in section 3.6 of the Declaration. Consequently, it is clear that Rohr does not disclose any superparamagnetic materials.

Applicants, therefore, submit that claims 1-19 and 21 are novel over Rohr, and respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

REJECTIONS UNDER 35 U.S.C. § 103

Claim 20 stands rejected under 35 U.S.C. § 103(a) for alleged obviousness over Weitschies *et al.* or Tan *et al.* or Rohr in view of Nelson *et al.* (U.S. Patent No. 5,962,641). Dependent claim 20 is patentable over the cited art for at least the reasons with respect to independent claim 1, as well as for novel and non-obvious features recited therein. Thus, claim 20 is in condition for allowance.

CONCLUSION

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant does not acquiesce to each of the Examiner's rejections and to each of the Examiner's assertions regarding what the cited references show or teach, even if not expressly discussed herein.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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Encloses: Declaration under 37 CFR § 1.132

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